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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,251	07/18/2006	William M. Clark	PU60698	8332

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SMITHKLINE BEECHAM CORPORATION
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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

NOTIFICATION DATE	DELIVERY MODE
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05/18/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No. 10/597,251	Applicant(s) CLARK ET AL.	
	Examiner Brenda L. Coleman	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-44 are pending in the application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-33 and 38, drawn to the process of preparing the benzofuran-2-carboxylic acid {(S)-3-methyl-1-[(4S,7R)-7-methyl-3-oxo-1-(pyridine-2-sulfonyl)-azepan-4-ylcarbamoyl]-butyl}-amide of Formula I and 3-methyl-N-[(1S)-3-methyl-1-({[(4S,7R)-7-methyl-3-oxo-1-(2-pyridinylsulfonyl)hexahydro-1H-azepin-4-yl]amino}carbonyl)butyl]furo[3,2-b]pyridine-2-carboxamide of Formula II.

Group II, claim(s) 34-37, drawn to the process of preparing the (2S)-2-[(2-benzofuranylcarbonyl)amino]-4-methylpentanoic acid compound of formula 3-5.

Group III, claim(s) 39-41, drawn to the process of preparing the N-[(3-methylfuro[3,2-b]pyridine-2-yl)carbonyl]-L-leucine compound of formula 6-3.

Group IV, claim(s) 42, drawn to the (R)-N-(α -methylallyl)phthalimide compound of formula 1-3.

Group V, claim(s) 42, drawn to the (R)-2-pyridinesulfonyl-N-([α -methylallyl)amine compound of formula 1-5.

Group VI, claim(s) 42, drawn to the 2-[(1S)-1-(2R)-oxiranyl-2-propenyl]-1H-isoindole-1,3(2H)-dione compound of formula 2-3.

Group VII, claim(s) 42, drawn to the N-[(2S,3S)-3-(1,3-dihydro-1,3-dioxo-2H-isoindol-2-yl)-2-hydroxy-4-pentenyl]-N-[(1R)-1-methyl-2-propenyl]-2-pyridinesulfonamide compound of formula 3-1.

Group VIII, claim(s) 43, drawn to the (3S,4S,7R)-4-(1,3-dihydro-1,3-dioxo-2H-isoindol-2-yl)-2,3,4,7-tetrahydro-7-methyl-1-(2-pyridinylsulfonyl)-1H-azepin-3-ol compound of formula 3-2.

Group IX, claim(s) 43, drawn to the (3S,4S,7R)-4-amino-2,3,4,5,6,7-hexahydro-7-methyl-(2-pyridinylsulfonyl)-1H-azepin-3-ol compound of formula 3-3.

Group X, claim(s) 44, drawn to the (3S,4S,7R)-4-amino-2,3,4,5,6,7-hexahydro-7-methyl-(2-pyridinylsulfonyl)-1H-azepin-3-ol compound of formula 3-4.

Group XI, claim(s) 44, drawn to the (2S)-2-[(2-benzofuranylcarbonyl)amino]-4-methylpentanoic acid compound of formula 3-5.

Group XII, claim(s) 44, drawn to the {(S)-1-[(3S,4S,7R)-3-hydroxy-7-methyl-1-(pyridine-2-sulfonyl)-azepan-4-ylcarbamoyl]-3-methyl-butyl}-amide compound of formula 3-6.

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the inventions of Groups I-XII are drawn to structurally dissimilar compounds, compositions and method of use of the compounds of formulae I and II. They are made and used independently. One does not require the other for their use. If, say, the benzofuran-2-carboxylic acid {(S)-3-methyl-1-[(4S,7R)-7-methyl-3-oxo-1-(pyridine-2-sulfonyl)-azepan-4-ylcarbamoyl]-butyl}-amide and 3-methyl-N-[(1S)-3-methyl-1-({[(4S,7R)-7-methyl-3-oxo-1-(2-pyridinylsulfonyl)hexahydro-1H-azepin-4-yl]amino}carbonyl)butyl]furo[3,2-b]pyridine-2-carboxamide of Group I, were anticipated, applicants would not acquiesce in the objection of any of the Groups II-XII there over or vice-versa and, thus, they are not linked to the same or corresponding special technical features.

The inventions I and II-XII are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product

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(MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful to prepare other substituted azepanes and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/
Primary Examiner, Art Unit 1624